IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CIPLA LTD., Plaintiff, v. BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, AND BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, Defendants.	Civil Action No. 22-300-MN [redacted] **PUBLIC VERSION FILED MARCH 14, 2022**

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Cipla Ltd. ("Plaintiff" or "Cipla"), by its attorneys brings this action against Defendants Boehringer Ingelheim Pharmaceuticals Inc. ("Boehringer, Inc."), Boehringer Ingelheim International GmbH ("Boehringer GmbH"), and Boehringer Ingelheim Pharma GmbH & Co. KG ("Boehringer Pharma," collectively, "Defendants" or "Boehringer") for declaratory judgment that Cipla's generic nintedanib esylate 100 mg and 150 mg capsules do not and will not infringe any valid claim of U.S. Patent No. 9,907,756 (the "'756 patent") and U.S. Patent No. 10,105,323 (the "'323 patent").

Nature of the Action

1. This case arises under the Hatch-Waxman Act, which governs the U.S. Food and Drug Administration's ("FDA's") approval of both new and generic drugs. *See* 21 U.S.C. § 355. The Hatch-Waxman Act allows an Abbreviated New Drug Application ("ANDA") holder to bring a declaratory judgment action seeking a declaration that ANDA holder's proposed drug product

will not infringe a patent listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book"). *See* 21 U.S.C. § 355(j)(5)(C)(i)(II). This declaratory judgment provision aims to, among other things, prevent brand-name drug companies from using tactics that forestall the competing generic drug makers from entering the market. *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008). For example and relevant here, "when generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the 'failure to market' provision and force the first generic to market." *Id.* (quoting 149 CONG. REC. S15885 (Nov. 25, 2003)).

2. Cipla has submitted ANDA No. 212609 ("Cipla's ANDA") to the FDA seeking approval to manufacture, use, import, offer for sale, and sell Cipla's nintedanib esylate, 100 mg and 150 mg capsules (equivalent to 120.40 mg and 180.60 mg nintedanib ethanesulfonate, respectively) as the active ingredient, as a generic equivalent to Boehringer Inc's Ofev® capsule as described in Cipla's ANDA ("Cipla's ANDA Products").

3. Boehringer has five patents listed in the FDA's Orange Book as covering Ofev: the '756 and '323 patents as well as U.S. Patent Nos. 7,119,093 (the "'093 patent"), 6,762,180 (the "'180 patent"), and 10,154,990 (the "'990 patent"). *See* Exhibit A, Orange Book Patent and Exclusivity Information for Ofev. Under the Hatch-Waxman Act, Cipla was required to submit patent certifications to each of the Orange Book patents listed for Ofev.

4. [redacted] *See* Exhibit B, Cipla's Patent Certifications Statement at 1. [redacted]

[redacted]

5. [redacted] *See* Exhibit B, Cipla's Patent Certifications Statement at 2.

6. Cipla's ANDA contains a paragraph IV ("PIV") certification that the '323 and '756 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Cipla's ANDA Pproducts. *See id.* at 1.

7. Cipla notified Boehringer of the PIV certification and provided an Offer of Confidential Access to relevant portions of its ANDA. *See* Exhibit C, Cipla's Notice Letter; Exhibit D, Cipla's Offer of Confidential Access; *see also*, 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. § 314.95.

8. Boehringer did not sue Cipla for patent infringement within 45 days of receiving notice of Cipla's PIV certification. *See* 21 U.S.C. § 355(j)(5)(B)(iii), (j)(5)(C).

9. Boehringer does not have a basis consistent with Fed. R. Civ. P. 11 to allege that Cipla's ANDA Products infringe any claim of the '756 or '323 patents. If Boehringer did have such a basis, it would have sued Cipla already.

10. To the extent Boehringer does contend Cipla's ANDA Products infringe any claim of the '756 or '323 patents, there is a substantial and continuing controversy between the parties, and a declaration that Cipla's ANDA Products do not infringe any valid claim of the '756 or '323 patents is both necessary and appropriate. Cipla needs certainty as to whether Cipla's ANDA Products infringe the claims of the '756 or '323 patents. By, among other things, listing the '756 and '323 patents in the Orange Book, but failing to bring an action for patent infringement,

Boehringer has injected uncertainty and insecurity into Cipla's pursuit of regulatory approval and commercialization of Cipla's ANDA Products.

11. Even if Boehringer does not contend that Cipla's ANDA Products infringe any claim of the '756 patent, there is still a substantial and continuing controversy between the parties, making a declaration of rights both necessary and appropriate, because another ANDA applicant's eligibility for 180-day exclusivity prevents the FDA from approving Cipla's ANDA Products. *See Teva Pharm. USA, Inc. v. Eisai Co.*, 620 F.3d 1341, 1347 (Fed. Cir. 2010), vacated on procedural grounds, 426 F. App'x 904 (Fed. Cir. 2011) ("We hold that this case presents an actual controversy. Here, as in *Caraco*, a favorable judgment 'would eliminate the potential for the [DJ patents] to exclude [Teva] from the drug market.'" (citation omitted)). Even where the patent owner provides a covenant not to sue to the subsequent applicant, there is still an actual controversy based on the potential for the patents to block that subsequent ANDA applicant from the market. *See id.* at 1345, 1348 n.3.

12. The first applicant to file a substantially complete ANDA containing a PIV certification to an Orange Book-listed patent and to provide appropriate notice to the NDA holder and patent owner for a particular generic product, is eligible for a 180-day period of generic marketing exclusivity against other companies that subsequently file ANDAs referencing the same branded drug product. *See* 21 U.S.C. § 355(j)(5)(B)(iv). If the FDA has deemed that a first ANDA applicant is eligible for 180-day exclusivity, the FDA will not grant final approval to any subsequently filed ANDA containing a PIV certification until 180 days after the date of the first commercial marketing of the drug by any first applicant. *See id.* § 355(j)(5)(B)(iv)(I).

13. An excerpt of FDA's "Paragraph IV Patent Certifications" dated November 2, 2021 set forth below shows that four ANDAs were submitted on October 15, 2018.

Paragraph IV Patent Certifications
November 2, 2021

DRUG NAME	DOSAGE FORM	STRENGTH	RLD/NDA	DATE OF SUBMISSION	NUMBER OF ANDAs SUBMITTED	180-DAY STATUS	180-DAY DECISION POSTING DATE	DATE OF FIRST APPLICANT APPROVAL	DATE OF FIRST COMMERCIAL MARKETING BY FTF	EXPIRATION DATE OF LAST QUALIFYING PATENT
Nicotine Polacrilex	Troche/Lozenge	2 mg and 4 mg	Commit							
Nicotine Polacrilex	Troche/Lozenge (Mini)	2 mg and 4 mg	Nicorette 22360	12/2/2015	1	Eligible	10/8/2019	2/7/2019	4/4/2019	6/14/2029
Nicotine Polacrilex	Gum	2 mg	Nicorette	1/22/2013						
Nicotine Polacrilex	Gum	4 mg	Nicorette	1/22/2013						
Nifedipine	Capsules	10 mg and 20 mg	Procardia 18482							
Nifedipine	Extended-release Tablets	30 mg, 60 mg and 90 mg	Adalat CC 20198							
Nifedipine	Extended-release Tablets	30 mg, 60 mg and 90 mg	Procardia XL 19684							
Nilotinib	Capsules	50 mg	Tasigna 22068	10/17/2019	1					4/7/2032
Nilotinib	Capsules	150 mg and 200 mg	Tasigna 22068	11/8/2013	1					7/18/2026
Nintedanib	Capsules	100 mg and 150 mg	Ofev 205832	10/15/2018	4					6/7/2029
Nitric Oxide	for Inhalation	100 ppm and 800 ppm	INOmax 20845	5/20/2014	1	Deferred	11/19/2019	10/2/2018	4/1/2019	1/6/2031
Nisoldipine	Extended-release Tablets	8.5 mg and 17 mg	Sular 20356	3/2/2009						
Nisoldipine	Extended-release Tablets	20 mg and 30 mg	Sular 20356	11/7/2007						
Nisoldipine	Extended-release Tablets	25.5 mg and 34 mg	Sular 20356	11/28/2008						
Nisoldipine	Extended-release Tablets	40 mg	Sular 20356	6/11/2007						
Nitrofurantoin Monohydrate/ Macrocrystals	Capsules	75 mg/25 mg	Macrobid 20064							
Nitroglycerin	Sublingual Tablets	0.3 mg, 0.4 mg, and 0.6 mg	Nitrostat 21134	10/19/2005	1	Extinguished	3/10/2020			9/16/2018
Nitroglycerin	Transdermal System	0.1 mg/hr	Transderm-Nitro 20144							

Exhibit E, Excerpts of Paragraph IV Patent Certifications at 51 (emphasis added).

14. The NDA holder submitted the ’323 patent for listing in the Orange Book on November 6, 2018, which is after the date of the date of submission of the first PIV certifications. Exhibit A, Orange Book Patent and Exclusivity Information for Ofev.

15. The “Expiration Date of Last Qualifying Patent,” June 7, 2029, is the expiration date of the ’756 patent.

16. According to the FDA’s website, none of the four ANDAs submitted have received final approval.

17. Accord Healthcare Inc. (“Accord”) received tentative approval on or around August 4, 2020. *See* Exhibit F, Accord’s ANDA Tentative Approval Letter. The FDA’s ANDA Tentative Approval letter states that Accord submitted its ANDA on October 15, 2018 and included PIV certifications to the ’756 and ’323 patents. *Id.*at 2. According to the FDA’s letter to Accord, the

NDA holder submitted the ’323 patent to Agency after the submission of Accord’s ANDA, and therefore, litigation involving the ’323 patent would not create a statutory stay of approval. *Id.* at 4 fn.1. The FDA’s ANDA Tentative Approval letter further states that Accord submitted PIII certifications to the ’180 and ’093 patents and a section viii statement for the ’990 patent. *Id.* at 2.

18. Glenmark Pharmaceuticals Limited (“Glenmark”) received tentative approval on or around June 22, 2021. *See* Exhibit G, Glenmark’s ANDA Tentative Approval Letter. The FDA’s ANDA Tentative Approval letter states that Glenmark submitted its ANDA on October 15, 2018. *Id.* at 1. Glenmark’s ANDA included a PIV certification to the ’756 and ’323 patents. *Id.* at 2. According to FDA’s letter to Glenmark, the NDA holder submitted the ’323 patent to the Agency after the submission of Accord’s ANDA, and litigation involving the ’323 patent would not create a statutory stay of approval. *Id.* at 4 fn.1. The FDA’s ANDA Tentative Approval letter further states that Glenmark submitted PIII certifications to the ’180 and ’093 patents and a section viii statement for the ’990 patent. *Id.* at 2.

19. On information and belief, at least one first applicant has eligibility for 180-day exclusivity on the 100 mg and 150 mg nintedanib capsules. On information and belief, unless the first applicants forfeit the 180-day exclusivity, the FDA will not approve Cipla’s ANDA Products until 180 days after a first applicant launches its 100 mg and 150 mg nintedanib capsules or the ’756 and ’323 patents expire in June 2029, whichever is earlier.

20. Congress, however, never intended the 180-day generic exclusivity period to improperly delay the start of generic competition. The Hatch-Waxman Act, therefore, provides various mechanisms to trigger forfeiture of the first applicant’s 180-day marketing exclusivity. The failure to market forfeiture provision, at issue here, requires, among other things, the entry of a final judgment of non-infringement or invalidity with respect to the patents against which a first

ANDA filer has filed and lawfully maintained a PIV certification, regardless of whether those patents are asserted against subsequent ANDA applicants. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

21. [redacted]

22. However, the FDA can grant Cipla final approval to its 100 mg and 150 mg nintedanib ANDA products [redacted] if Cipla "triggers" the failure to market forfeiture of the first applicants' exclusivity by obtaining a declaratory judgment of non-infringement of the '756 patent. As such, a subsequent applicant has an incentive to file a declaratory judgment action to obtain patent certainty and be able to launch its product. It will trigger the failure to market forfeiture provision, forcing the first applicants to either launch its product and utilize the 180-day exclusivity, or forfeit the 180-day exclusivity by failing to market within 75 days of a final court decision under 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb).

23. Cipla has a right to engage in making, using, offering to sell, and selling its products described in Cipla's ANDA on and after [redacted] without a license from Boehringer.

24. Cipla's declaratory judgment action is necessary to remove the '756 and '323 patents as barriers to Cipla's market entry for nintedanib capsules because but for Boehringer's decision to cause the '756 and '323 patents to be listed in the Orange Book, final FDA approval of Cipla's ANDA Products would not be delayed beyond [redacted]. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I).

25. Without a judgment, Cipla will be barred from selling its nintedanib capsules—possibly until 2029—causing injury to Cipla by depriving it of sales revenue that it could have earned beginning on [redacted].

An Article III Case Or Controversy Exists

26. There is an actual and ongoing controversy between Cipla and Boehringer with respect to infringement of the '756 and '323 patents that can be resolved by a declaratory judgment from this Court. The first applicant(s) to submit an ANDA referencing 100 mg and 150 mg Ofev capsules and retain eligibility for 180-day exclusivity blocks approval of any subsequently filed ANDA, such as Cipla's ANDA. A judgment of noninfringement will trigger the failure to market forfeiture of the first applicants' exclusivity, allowing Cipla to bring Cipla's ANDA Products to market at the earliest possible date. This controversy is of sufficient immediacy and reality to empower the Court to issue a declaratory judgment. *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1362–63 (Fed. Cir. 2015) (holding the statute authorizes a declaratory judgment action to trigger forfeiture).

27. The present dispute between Cipla and Boehringer satisfies the three-part framework for determining whether an action presents a justiciable Article III controversy: (1) the plaintiffs have standing; (2) the issues are ripe for adjudication; and (3) the case is not rendered moot. *Caraco*, 527 F.3d at 1291.

28. Standing requires three elements: (1) an alleged injury in fact—"a harm suffered by the plaintiff that is 'concrete' and actual or imminent, not 'conjectural' or 'hypothetical'"; (2) causation—"a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant"; and (3) redressability—"a likelihood that the requested relief will redress the alleged injury." *Id.* (citing *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102–03 (1998)).

29. In a recent Hatch-Waxman action in the District of New Jersey, Piramal filed a declaratory judgment action against Novartis seeking a court decision that its 180 mg deferasirox product did not infringe the '209 patent. *See Piramal Healthcare UK Ltd. v. Novartis Pharm. Corp.*, No. 19-12651, 2020 WL 1074765 at *3. Novartis attempted to eliminate subject matter jurisdiction by providing a covenant not to sue Piramal for infringement of the '209 patent and filed a motion to dismiss for lack of subject matter jurisdiction. *Id.* at *3–5. Piramal explained that a blocking injury existed and came forward with substantial evidence indicating that another ANDA filer (whose name remains confidential in accordance with FDA policy) retains the right to the 180-day commercial exclusivity as to the generic 180 mg deferasirox product, which precluded Piramal from obtaining final FDA approval of its product. *Id.* at *11. Novartis attempted to rebut this showing by arguing that "the FDA must be wrong" (*id.* at *12), but "jump[ed] to conclusions and dismiss[ed] the FDA database indicating that existence of a 180-day exclusivity period for the subject drug" (*id.* at 15). The Court found that subject matter jurisdiction existed by virtue of a blocking injury and denied Novartis's motion to dismiss for lack of subject matter jurisdiction with the opportunity to renew it if it could find "concrete evidence" that no injury exists. *Id.* at *16–17.

30. At least Accord and Glenmark are first applicants and, upon information and belief, remain eligible for the 180-day exclusivity as first applicants. The 180-day exclusivity of one or more first applicants would preclude Cipla from marketing Cipla's ANDA Products until the exclusivity expires or is forfeited. Under the Hatch-Waxman Act, an ANDA filer is not legally free to enter the market without FDA approval. Boehringer's listing of the '756 patent, Cipla's filing of ANDA No. 212609 with the FDA under 21 U.S.C. § 355(j) seeking approval to market generic versions of 100 mg and 150 mg nintedanib capsules with a PIV certification to the '756

patent, and Boehringer's failure to bring suit against Cipla in connection with Cipla's filing of its ANDA for 100 mg and 150 mg nintedanib capsules is blocking generic competition in general and will block final approval of Cipla's ANDA [redacted]. Thus, the listing of the '756 patent creates a bottleneck to Cipla's 100 mg and 150 mg nintedanib capsules causing injury-in-fact to Cipla. *Teva Pharm. USA, Inc.*, 620 F.3d at 1347 ("*Caraco* holds that the exclusion of non-infringing generic drugs from the market can be a judicially cognizable injury-in-fact.").

31. If approval of Cipla's ANDA is blocked by 180-day marketing exclusivity, Cipla will suffer monetary harm because it will be unable to enter the market at the earliest possible date under the applicable statutory and FDA regulatory provisions and be deprived of an opportunity to compete in the market for 100 mg and 150 mg nintedanib capsules beginning on [redacted]

32. Cipla's injury is directly traceable to Boehringer because, for example, but for Boehringer's listing the '756 patent in the Orange Book, the FDA would not have determined that an ANDA filer is entitled to 180 days of marketing exclusivity for nintedanib capsules based on the listing of the '756 patent in the Orange Book, blocking final approval of Cipla's ANDA. Boehringer has created a barrier to FDA approval of Cipla's ANDA.

33. Boehringer also chose not to sue Cipla after receiving notice of Cipla's PIV certification. Suing Cipla would have allowed Cipla to obtain a final judgment of non-infringement on the '756 patent. Boehringer has apparently chosen not to sue other applicants. But for Boehringer avoiding litigating infringement of the '756 patent, final approval of Cipla's ANDA Products would not be delayed. But for Boehringer's actions, Cipla's market entry for its 100 mg and 150 mg nintedanib capsules would not be delayed by any first applicant's 180-day exclusivity.

34. The 180-day exclusivity, combined with the Boehringer's avoidance of litigation concerning the validity or infringement of the '756 patent, delays FDA approval of a subsequent ANDA and thus delays a subsequent applicant's entry into the market. This constitutes a "blocking injury," which is a sufficient injury-in-fact to satisfy Cipla's standing to sue Boehringer.

35. Cipla's injury is redressable. Judgment of non-infringement of the '756 patent from this Court will activate either the launch of the drug product by a first applicant or forfeiture of the first applicant's exclusivity period allowing Cipla and other generic competitors to enter the market at the earliest possible date. In other words, the barrier to final approval can be cleared by a judgment of non-infringement.

36. If Cipla is able to obtain a final judgment of non-infringement with respect to all claims of the '756 patent, then the first applicants will have 75 days to launch their respective product to avoid forfeiture of the 180-day exclusivity.

37. Upon information and belief, all of the first applicants have submitted a PIII certification to the '093 and '180 patents.

38. Upon information and belief, all of the first applicants have submitted a section viii statement with respect to the '990 patent.

39. [redacted].

40. Alternatively, if one or both of the '180 and '093 patents were subject to a PIV certification for at least one first applicant, then a final judgment of non-infringement on the '756 patent in favor of Cipla would require the first applicants to launch within 75 days of expiry of the '180 patent to avoid forfeiture.

41. Absent a judgment from this Court declaring that Cipla's ANDA Products do not infringe the '756 and '323 patents, Cipla will be unable to sell its generic nintedanib capsules possibly until 2029, thereby injuring Cipla by depriving it of sales revenue that it could earn for that period of time. Were Cipla free to market its generic nintedanib capsules at the earliest possible date, it would earn substantial profits.

42. The action is ripe. Determining whether an action is "ripe" requires an evaluation of "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Caraco*, 527 F.3d at 1278 (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)). [redacted]

43. The mootness doctrine requires that the parties must maintain a requisite personal stake. Only a judgment from this Court through an adjudication or consent decree can alleviate the harm to Cipla. Any covenant not to sue would not moot this case because Cipla's 100 mg and 150 mg nintedanib capsules will still be blocked from the market, preventing Cipla from selling that product. *Caraco*, 527 F.3d at 1297 (quoting *MedImmune. Inc. v. Genentech, Inc.*, 549 U,S, 118,

127 (2007)) (holding that "even after a covenant not to sue has been granted, the dispute as to infringement or invalidity of the relevant Orange–Book–listed patents constitutes a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.").

The Parties

44. Plaintiff Cipla Ltd. is a corporation organized under the laws of India, having a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai – 400013, Maharashtra, India.

45. On information and belief, Defendants currently market nintedanib 100 mg and 150 mg capsules, under the trade name Ofev pursuant to FDA's approval of NDA No. 205832.

46. On information and belief, Defendant Boehringer Ingelheim Pharma GmbH & Co. KG is the assignee of record with the United States Patent and Trademark Office for the '756 patent.

47. On information and belief, Defendant Boehringer Ingelheim International GmbH is the assignee of record with the United States Patent and Trademark Office for the '323 patent.

Jurisdiction and Venue

48. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) based on an actual, substantial, and continuing justiciable case or controversy between Cipla and Boehringer arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, 21 U.S.C. § 355(j)(5)(C), and 35 U.S.C. § 271(e)(5).

49. This Court has personal jurisdiction over Boehringer Ingelheim Pharmaceuticals, Inc. because, on information and belief, Boehringer Ingelheim Pharmaceuticals, Inc. is incorporated under the laws of the state of Delaware and conducts business in and has regular and

systematic contact with Delaware. On information and belief, Boehringer Ingelheim Pharmaceuticals, Inc. has purposefully availed itself to this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of Delaware and deriving revenue from such activities.

50. On information and belief, Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim International GmbH have sued for patent infringement in this District, and has therefore availed themselves to this forum in at least the following cases: *Boehringer Ingelheim Pharm. Inc. et al. v. Sun Pharm. Industries Limited et al.*, No. 21-1573 (D. Del. Nov. 5, 2021); *Boehringer Ingelheim Pharm. Inc. v. Lupin Ltd. et al.*, No. 21-1486 (D. Del. Oct. 22, 2021); *Boehringer Ingelheim Pharm. Inc. et al. v. Aurobindo Pharm. Ltd. et al.*, No. 21-1485 (D. Del. Oct. 22, 2021); *Boehringer Ingelheim Pharm. Inc. et al. v. Annora Pharm. Priv. Ltd., et al.*, No. 20-0277 (D. Del. Feb. 25, 2020); *Boehringer Ingelheim Pharm. Inc. et al. v. Alembic Pharm., Ltd. et al.* No. 19-1885 (D. Del. Oct. 7, 2019); *Boehringer Ingelheim Pharm. Inc. et al. v. Macleods Pharm., Ltd. et al.*, No. 19-1864 (D. Del. Oct. 3, 2019); *Boehringer Ingelheim Pharm. Inc. et al. v. MSN Laboratories Priv. Ltd. et al.*, No. 19-1865 (D. Del. Oct. 3, 2019); *Boehringer Ingelheim Pharm. Inc. et al. v. Laurus Labs, Ltd. et al.*, No. 19-1596 (D. Del. Aug. 28, 2019); *Boehringer Ingelheim Pharm. Inc. et al. v. Aizant Drug Research Solutions Pvt. Ltd.*, No. 19-1492 (D. Del. Aug. 9, 2019); *Boehringer Ingelheim Pharm. Inc. et al. v. Alkem Laboratories Ltd. et al*., No. 19-1493 (D. Del. Aug. 9, 2019).

51. This Court has personal jurisdiction over Boehringer Ingelheim Pharma GmbH & Co. KG based on Boehringer Ingelheim Pharma GmbH & Co. KG's systematic and continuous contacts with Delaware. On information and belief, Boehringer Ingelheim Pharma GmbH & Co.

KG has conducted and continues to conduct business directly or through its subsidiaries, agents, and alter egos, including Boehringer Ingelheim Pharmaceuticals, Inc. in this District.

52. On information and belief, Boehringer Ingelheim Pharma GmbH & Co. KG has purposefully availed itself to this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of Delaware and deriving revenue from such activities.

53. On information and belief, Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim Pharmaceuticals, Inc., and Boehringer Ingelheim International GmbH have sued for patent infringement in this District, and has therefore availed themselves to this forum in at least the following cases: *Boehringer Ingelheim Pharmaceuticals Inc. et al v. Macleods Pharmaceuticals Ltd. et al*, No. 19-01772 (D. Del. Sept. 20, 2019); *Boehringer Ingelheim Pharma GmbH & Co. KG et al v. Teva Pharmaceuticals USA, Inc. et al*, No. 15-00048 (D. Del. Jan. 16, 2015); and *Boehringer Ingelheim Pharma GmbH & Co. KG et al v. Barr Laboratories Inc. et al*, No. 7-00432 (D. Del. July 11, 2007).

54. This Court also has personal jurisdiction over Boehringer Ingelheim Pharma GmbH & Co. KG pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Cipla's claims arise under federal law; (2) Boehringer Ingelheim Pharma GmbH & Co. KG is a foreign corporation; and (3) Boehringer Ingelheim Pharma GmbH & Co. KG has sufficient contacts with the United States. These contacts include, but are not limited to, Boehringer Ingelheim Pharma GmbH & Co. KG's contacts through its subsidiaries, agents, and/or alter egos, including Boehringer Ingelheim Pharmaceuticals, Inc. directing the manufacture, importation, offer for sale, and/or sale of pharmaceutical products that are distributed throughout the United States, applying for and obtaining U.S. patents, and litigating cases in United States courts as mentioned above.

55. This Court has personal jurisdiction over Boehringer International GmbH based on Boehringer Ingelheim International GmbH's systematic and continuous contacts with Delaware. On information and belief, Boehringer Ingelheim International GmbH has conducted and continues to conduct business directly or through its subsidiaries, agents, and alter egos, including Boehringer Ingelheim Pharmaceuticals, Inc. in this District.

56. On information and belief, Boehringer Ingelheim International GmbH has purposefully availed itself to this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of Delaware and deriving revenue from such activities.

57. On information and belief, and as stated in paragraphs 53 and 56 Boehringer Ingelheim International GmbH has sued for patent infringement in this District, and has therefore availed themselves to this forum.

58. This Court also has personal jurisdiction over Boehringer International GmbH pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Cipla's claims arise under federal law; (2) Boehringer Ingelheim International GmbH is a foreign corporation; and (3) Boehringer Ingelheim International GmbH has sufficient contacts with the United States. These contacts include, but are not limited to, Boehringer Ingelheim International GmbH's contacts through its subsidiaries, agents, and/or alter egos, including Boehringer Ingelheim Pharmaceuticals, Inc. directing the manufacture, importation, offer for sale, and/or sale of pharmaceutical products that are distributed throughout the United States, applying for and obtaining U.S. patents, and litigating cases in United States courts as mentioned above.

59. Venue is proper in this Court pursuant to 28 U.S.C. § 1391.

Regulatory Background

60. Congress passed the Drug Price Competition and Patent Term Restoration Act in 1984, which is commonly known as the Hatch-Waxman Act. Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). The Hatch-Waxman Act represented a compromise between the generic and branded pharmaceutical industries, and, among other things, created avenues to encourage and allow for generic products to enter the market, while preserving incentives for development of innovative and new branded products. *See* H.R. Rep. No. 98-587, pt. 1 at 14–15 (1984).

61. Under this framework, a company seeking approval of a new drug must submit an NDA to the FDA. 21 U.S.C. § 355. In addition to this application, the brand company must identify the patents that cover the drug substance, the drug product, and/or the method of using the drug product. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2). The FDA will list these patents in the Orange Book once the NDA is approved. Generally, this new branded drug is referred to as a reference-listed drug.

62. A company seeking approval of a generic version of the branded drug must also submit an application, known as an ANDA. As an "abbreviated" application, the generic company may rely on the branded company's preclinical and clinical data to support the safety and efficacy of the drug if the generic product is "bioequivalent" to the reference-listed drug. 21 U.S.C. § 355(j)(4)(F).

63. A generic company must include certain certifications to the patents listed in the Orange Book for the reference-listed drug in its ANDA. These certifications are as follows: (I) there are no patents in the Orange Book; (II) there are patents listed in the Orange Book, but they have expired; (III) the generic company will not market its generic product before the patents listed in the Orange Book expire; and (IV) the generic company believes the listed patent is invalid,

unenforceable, or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV); 21 C.F.R. § 314.94(a)(12). The last of these is commonly referred to as a PIV certification.

64. A generic company must certify to each listed patent, but these certifications can be different. For example, a generic company may opt to wait for the expiration of patent A that will expire before the generic company anticipates it will receive approval, but may also submit a PIV certification for patent B that it believes it does not infringe.

65. If a generic company's ANDA contains a PIV certification, the generic company must notify the NDA holder and the patentee in writing of its PIV certification. *See* 21 U.S.C. § 355(j)(2)(B). This is generally referred to as a "Notice Letter." The Notice Letter will include a detailed statement of the factual and legal bases that the patent is invalid and/or not infringed. *Id.* § 355(j)(2)(B)(iv).

66. The Notice Letter usually also includes an Offer of Confidential Access to relevant portions of the ANDA, which allows the NDA holder and patent owner to review the information subject to confidentiality restrictions, to determine whether the ANDA product will infringe an Orange Book listed patent. *Id.* § 355(j)(5)(C)(i)(III).

67. The Hatch-Waxman Act also created a framework to allow for generic and branded companies to resolve their patent disputes promptly. Therefore, once the NDA holder and patentee receive the Notice Letter, they may bring suit against the generic company for patent infringement. *Id.* § 355(j)(5)(B)(iii). The NDA holder and patentee have an incentive to file suit within 45 days because if they do, the suit triggers an automatic 30-month stay of FDA approval of the ANDA. *Id.*

68. If the generic company serves the Notice Letter, along with an Offer of Confidential Access, and neither the NDA holder nor the patent owner file suit within 45 days, the generic company may bring a declaratory judgment action to obtain patent certainty. *Id.* § 355(j)(5)(C)(i).

69. Generic companies also have incentives to promptly file their generic applications. The Hatch-Waxman Act qualifies the first applicant who files a substantially complete ANDA containing a PIV certification to an Orange Book listed patent (known as a "first applicant") an 180-day exclusivity period of marketing. *Id.* § 355(j)(5)(B)(iv). There can be more than one first applicant if multiple generic companies filed their ANDAs on the first day an ANDA is filed. The 180-day exclusivity period will not begin to run until the first applicant markets its product. During this period of exclusivity, subsequent ANDA filers may not receive final approval[1] until the first applicant's exclusivity runs or is forfeited. *Id.* § 355(j)(5)(B)(iv).

70. This 180-day exclusivity period can be forfeited, in which case the exclusivity will no longer prevent the FDA from approving a subsequently filed ANDA. Congress enacted the Medicare Modernization Amendments to the Hatch-Waxman Act, which included various scenarios where a first applicant would forfeit its 180-day exclusivity that generally include (1) failure to market; (2) withdrawal of application; (3) amendment of PIV certification; (4) failure to obtain tentative approval; (5) agreement with another applicant, NDA holder, or patentee that violates antitrust laws; and (6) expiration of all Orange Book listed patents that qualified the first applicant for exclusivity. *See id.* § 355(j)(5)(D); *see also* CENTER FOR DRUG EVALUATION AND RESEARCH ET AL., GUIDANCE FOR INDUSTRY: 180-DAY EXCLUSIVITY

[1] The FDA will not finally approve an ANDA if there are unexpired patents or if there are applicants eligible for exclusivities. An ANDA holder in this situation would receive "tentative approval," and would not be able to market the product until it receives final approval. 21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd).

QUESTIONS AND ANSWERS (2017), available at https://www.fda.gov/media/102650/download.

71. Congress authorized declaratory judgment actions by subsequent ANDA applicants to trigger forfeiture of the first applicant's 180-day exclusivity by obtaining a judgment of non-infringement, invalidity, or unenforceability. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA); *see also Caraco*, 527 F.3d at 1284 ("subsequent Paragraph IV ANDA filers can trigger the first Paragraph IV ANDA filer's 180-day exclusivity period via the court-judgment trigger."). As explained by a Court in this Circuit, "[t]he 180-day exclusivity, combined with the branded drug manufacturer's avoidance of litigation concerning the validity or infringement of an Orange-Book-listed patent, delays FDA approval of a subsequent ANDA and thus delays a subsequent applicant's entry into the market." *Piramal*, 2020 WL 1074765 at *9 (citing *Caraco*, 527 F.3d at 1285).

Cipla's Nintedanib Capsules are Blocked From Final Approval

72. Boehringer Ingelheim Pharmaceuticals Inc. holds the NDA for Ofev (nintedanib), 100 mg and 150 mg capsules that are indicated to slow the rate of decline in pulmonary function in patients with systemic sclerosis associated interstitial lung disease (SSc-ILD) and for the treatment of idiopathic pulmonary fibrosis (IPF) and chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.

73. At the time Cipla filed its ANDA, five patents were listed in the Orange Book in connection with Ofev. Exhibit A, Orange Book Patent and Exclusivity Information for Ofev. Boehringer requested the listing of the patents in the Orange Book in connection with Ofev, where "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1), (c)(2). Cipla filed PIV patent certifications to the '756 and '323 patents [redacted]

[redacted]

[redacted]

74. Cipla's PIV certification to the '756 and '323 patents, certifies that the '756 and '323 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of Cipla's ANDA products. Exhibit B, Cipla's Patent Certifications Statement at 1. The '756 patent expires on June 7, 2029 and the '323 patent expires on June 4, 2029. Exhibit A, Orange Book Patent and Exclusivity Information for Ofev.

75. [redacted]

76. [redacted]

77. [redacted]

[2] *See* Exhibit D, Offer of Confidential Access at 1.

78. Although FDA does not disclose the identity of the first applicant, FDA will publish the date of submission of the first substantially complete ANDA containing a PIV certification for each product. *See* Exhibit E, Excerpt of Paragraph IV Patent Certifications. For Ofev, FDA reports the date of submission as October 15, 2018. *Id.* at 51.

79. On information and belief, the first applicant submitted a substantially complete ANDA containing a PIV certification for the 100 mg and 150 mg nintedanib capsules on October 15, 2018. The FDA has not determined that a first applicant's 180-day marketing exclusivity has been extinguished.

80. Without a final decision by a court triggering the failure to market forfeiture provision, later filed ANDAs cannot obtain final approval and subsequently enter the market for nintedanib capsules until the expiration of the '756 patent (June 2029) or 180 days after the first commercial marketing of the first applicant's product.

81. Cipla submitted its ANDA after October 15, 2018, and is a subsequent filer. As discussed above, as a subsequent filer, Cipla is blocked from marketing its 100 mg and 150 mg nintedanib capsules.

Cipla's ANDA Product

82. Cipla has submitted an ANDA with the FDA seeking approval to manufacture and sell a generic version of Boehringer's Ofev (nintedanib), 100 mg and 150 mg capsules as described in Cipla's ANDA No. 212609. Exhibit H, Excerpt of Cipla's Shared Materials.

83. [redacted]

Cipla's Nintedanib Capsules Do Not Infringe Any Claim of the '756 and '323 Patents

84. Cipla's ANDA Products do not infringe any claim of the '756 patent literally or under the doctrine of equivalents.

85. "To prove infringement, the patentee must show that an accused product embodies all limitations of the claim either literally or by the DOE [i.e., doctrine of equivalents]." *Amgen Inc. v. F. Hoffman-La Roche, Ltd.*, 580 F.3d 1340, 1374 (Fed. Cir. 2009) (citations omitted). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Id.*

Cipla Does Not Literally Infringe the '756 Patent

86. The '756 patent, entitled "Capsule pharmaceutical dosage form comprising a suspension formulation of an indolinone derivative," is directed to compositions of nintedanib ethanesulphonate and attached hereto as Exhibit I. '756 patent at col. 1, ll. 6–15.

87. The '756 patent issued with 8 claims, as reproduced below, of which claims 1 and 6 are independent.

> 1. A formulation of the active substance 3-Z-[1-(4-(N-((4-methyl-piperazin-1-yl)-methycarbonyl)-N-methyl-amino)-anilino)-1-phenyl-methylene]-6-methoxycarbonyl-2-indolinone-monoethanesulphonate which comprises a lipid suspension of the active substance in 1 to 90 wt.% of medium chain triglycerides, 1 to 30 wt.% of hard fat and 0.1 to 10 wt.% of lecithin.
>
> 2. A capsule comprising a capsule shell and a capsule formulation, wherein the capsule formulation comprises the formulation in accordance with claim 1.
>
> 3. The capsule according to claim 2, wherein the capsule is a soft gelatin capsule.
>
> 4. The capsule according to claim 2, wherein the capsule shell comprises glycerol as plasticizing agent.
>
> 5. The capsule according to claim 2, wherein the capsule is a hard gelatin or a hydroxypropylmethylcellulose (HPMC) capsule, a polyvinyl alcohol polymer capsule or a pullulan capsule, optionally with a sealing or banding.

> 6. A lipid suspension consisting essentially of 3-Z-[1-(4-(N-((4-methyl-piperazin-1-yl)-methycarbonyl)-N-methyl-amino)-anilino)-1-phenyl-methylene]-6-methoxycarbonyl-2-indolinone-monoethanesulphonate, medium chain triglycerides, hard fat and lecithin, wherein the medium chain triglycerides, hard fat and lecithin are present in the liquid suspension in the following amounts:
>
> 1 to 90 wt.% of medium chain triglycerides,
> 1 to 30 wt.% of hard fat, and
> 0.1 to 10 wt.% of lecithin.
>
> 7. A capsule comprising a capsule shell and a capsule formulation, wherein the capsule formulation comprises the lipid suspension in accordance with claim 6.
>
> 8. The capsule according to claim 7, wherein the capsule is a soft gelatin capsule.

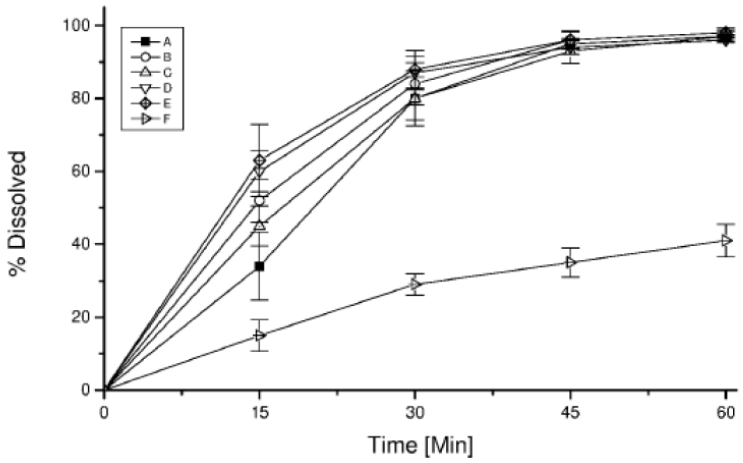
88. Independent claims 1 and 6 of the '756 patent recite a "lipid suspension" comprising "3-Z-[1-(4-(N-((4-methyl-piperazin-1-yl)-methycarbonyl)-N-methyl-amino)-anilino)-1-phenyl-methylene]-6-methoxycarbonyl-2-indolinone-monoethanesulphonate," i.e., nintendanib ethanesulphonate, "1 to 90 wt.% of medium chain triglycerides, 1 to 30 wt.% of hard fat and 0.1 to 10 wt.% of lecithin." *Id.* at cl. 1, 6.

89. The '756 specification states that "[l]ecithin is a common excipient for carrier-systems in soft gelatin capsules. It is used as a glidant of the highly concentrated suspension during encapsulation, prevents blocking of ducts and pumps and ensures high mass uniformity of the encapsulated formulation." *Id.* at col. 7, ll. 50–54. Moreover, lecithin "acts as a surfactant, which may improve distribution of the formulation-droplets during *in-vitro* dissolution testing as well as *in-vivo* for drug resorption. Furthermore, it may also improve wetting of the active substance crystals." *Id.* at col. 7, ll. 54–59.

90. The specification further states that "[i]t was surprisingly found that lecithin, up to a certain content, is useful to improve the dissolution behaviour of the finished capsules. Exceeding amounts do not show an additional benefit during *in-vitro* dissolution testing, as shown in FIG. 2."

Id. at col. 7, ll. 60–63 (emphasis added). Figure 2, reproduced below, shows the *in-vitro* dissolution behavior (measured as % dissolution) over time (in minutes) of soft gelatin nintedanib capsules containing: (A) 30% of the preferred amount of lecithin; (B); 75% of the preferred amount of lecithin; (C) 90% of the preferred amount of lecithin; (D) 100% of the preferred amount of lecithin; (E) 200% of the preferred amount of lecithin; and (F) 0% lecithin.

Figure 2



91. During the prosecution of the ’756 patent, the examiner rejected certain pending claims as obvious, or anticipated by the prior art. *See* Exhibit J, April 20, 2017 Office Action at 1, 3–9. In response, the applicant amended claim 1 to further require a “lipid suspension of the active substance in 1 to 90 wt.% of medium chain triglycerides, 1 to 30 wt.% of hard fat and ***0.1 to 10 wt.% of lecithin***.” Exhibit K, August 17, 2017 Response at 2 (emphasis added).

92. Claims 1–8 of the ’756 patent require, either directly or indirectly, a lipid suspension of nintedanib ethanesulphonate comprising “0.1 to 10 wt.% of lecithin,” among other excipients.

93. [redacted].

94. [redacted]

95. [redacted], and therefore do not literally infringe claims 1–8 of the '756 patent. *See* Exhibit H, Excerpt of Cipla's Shared Materials.

96. The ANDA specification may directly resolve the infringement inquiry because it defines a proposed generic product such that it either meets the limitations of an asserted patent claim or is outside the scope of the claim. *See Ferring B.V. v. Watson Labs., Inc.-Florida*, 764 F.3d 1401, 1408 (Fed. Cir. 2014).

Cipla Does Not Infringe the '756 Patent Under the Doctrine of Equivalents

97. Concluding that any weight percent amount of lecithin in a nintedanib suspension that is outside the claimed range of 0.1% to 10% w/w is equivalent to using 0.1% to 10% w/w of lecithin would vitiate this claim limitation. *See Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 29 (1997). The patentee has explicitly touted the advantages of using 0.1 to 10% w/w of lecithin in a lipid nintedanib suspension. In particular, the '756 specification provides that "[i]t was surprisingly found that lecithin, up to a certain content, is useful to improve the dissolution behaviour of the finished capsules." Exhibit I, '756 patent at col. 7, ll. 60–64 (emphasis added). The specification further states that amounts of lecithin exceeding those claimed by the '756 patent "do not show an additional benefit during *in-vitro* dissolution testing." *Id.* Because nintedanib suspensions containing more than 10% w/w of lecithin were foreseeable to the patentee but not literally claimed in the '756 patent, a finding of equivalents would vitiate this claim limitation. *See, e.g., Sage Products, Inc. v. Devon Industries, Inc.*, 126 F.3d 1420, 1424–25 (Fed. Cir. 1997) ("For a patentee who has claimed an invention narrowly, there may not be infringement

under the doctrine of equivalents in many cases, even though the patentee might have been able to claim more broadly. If it were otherwise, then claims would be reduced to functional abstracts, devoid of meaningful structural limitations on which the public could rely"). As such, a nintedanib suspension comprising a weight percent amount of lecithin outside the claimed range of 0.1% to 10% w/w is substantially different than, and not equivalent to, a suspension with 0.1% to 10% w/w lecithin.

98. In addition, the doctrine of prosecution history of estoppel bars the patentee from asserting substantial equivalence between a nintedanib suspension containing 0.1% to 10% w/w lecithin and a suspension containing a weight percent amount of lecithin outside the claimed range of 0.1% to 10% w/w.

99. During prosecution of the '756 patent, and in response to anticipation and obviousness rejections, the patentee amended the claims to specifically require a "lipid suspension of the active substance in 1 to 90 wt.% of medium chain triglycerides, 1 to 30 wt.% of hard fat and ***0.1 to 10 wt.% of lecithin***." Exhibit K, August 17, 2017 Response at 2, 5–9 (emphasis added).

100. The patentee made this amendment and argued that the prior art cited by the examiner did not teach or even suggest using 0.1 to 10% w/w of lecithin, or that using 0.1 to 10% w/w lecithin would have an "advantageous effect on the dissolution profile when included in a lipid suspension." *Id.* at 6–7 ("And even if Munzert et al. suggest a lipid suspension comprising lecithin (which it does not), ***nowhere does Munzert et al. describe or even suggest any formulation that is a lipid suspension comprising . . . 0.1 to 10 wt.% of lecithin*** as recited in amended claim 1") (emphasis added) (internal quotations omitted). Indeed, the examiner allowed the claims on the basis that the prior art did not disclose a "lipid suspension of the ***instant amounts***

of indolinone, medium chain triglycerides, hard fat and ***lecithin***." Exhibit L, January 17, 2018 Notice of Allowance at 3 (emphasis added).

101. After the applicant added the 0.1 to 10% w/w of lecithin limitation to the claims the examiner allowed the claims.

102. Adding that limitation narrowed the claims, and was a clear and unmistakable surrender of all components and amounts other than those components and amounts listed in the claim. As a result, the patentee cannot recapture the scope of the claims given up during prosecution. *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1251 (Fed. Cir. 2000).

Cipla Does Not Literally Infringe the '323 Patent

103. The '323 patent, entitled "Pharmaceutical dosage form for immediate release of an indolinone derivative," is directed to compositions of nintedanib ethanesulphonate and attached hereto as Exhibit M. '323 patent at col. 1, ll. 5–10.

104. The '323 patent issued with 10 claims, as reproduced below, of which claim 1 is the only independent claim.

> 1. A pharmaceutical dosage form which is a viscous lipid suspension formulation comprising:
>
> 10 to 50 wt. % of the active substance 3-Z-[1-(4-(N-((4-methyl-piperazin-1-yl)-methycarbonyl)-N-methyl-amino)-anilino)-1-phenyl-methylene]-6-methoxycarbonyl-2-indolinone-monoethanesulphonate,
>
> 10 to 70 wt.% of medium chain triglycerides;
>
> 10 to 30 wt.% of hard fat; and
>
> 0.25 to 2.5 wt.% of lecithin,
>
> which delivers an immediate release profile in which not less than 70% (Q65%) of the active substance is dissolved in 60 minutes in vitro under the following in vitro dissolution conditions according to European Pharmacopeia 6.2: Apparatus 2 (paddle), dissolution medium with 0.1 M HCl (pH 1) and stirring speed of 50 to 150 rpm, at a temperature of 37° C.
>
> 2. The pharmaceutical dosage form according to claim 1, wherein it is an orally deliverable dosage form.

3. The pharmaceutical dosage form according to claim 2, wherein it is in the form of a capsule.

4. The pharmaceutical dosage form according to claim 3 in the form of a soft gelatine capsule comprising 50 mg of active substance free base equivalent selected from the group consisting of compositions A, B and C:

Ingredients	Formulation A mg per capsule	Formulation B mg per capsule	Formulation C mg per capsule
Active Substance*	60.20	60.20	60.20
Triglycerides, Medium-chain	40.95	53.70	54.00
Hard fat	38.25	25.50	25.50
Lecithin	0.60	0.60	0.30
Gelatin	72.25	72.25	72.25
Glycerol 85%	32.24	32.24	32.24
Titanium dioxide	0.20	0.20	0.20
Iron oxide A	0.32	0.32	0.32
Iron oxide B	0.32	0.32	0.32
Total Capsule Weight	245.33	245.33	245.33.

5. The pharmaceutical dosage form according to claim 3 in the form of a soft gelatine capsule comprising 75 mg of active substance free base equivalent selected from the group consisting of compositions A, B and C:

Ingredients	Formulation A mg per capsule	Formulation B mg per capsule	Formulation C mg per capsule
Active Substance*	90.3	90.3	90.3
Triglycerides, Medium-chain	61.425	80.55	80.1
Hard fat	57.375	38.25	38.25
Lecithin	0.9	0.9	1.35
Gelatin	107.11	107.11	107.11
Glycerol 85%	46.84	46.84	46.84
Titanium dioxide	0.35	0.35	0.35
Iron oxide A	0.058	0.058	0.058
Iron oxide B	0.16	0.16	0.16
Total Capsule Weight	364.518	364.518	364.518.

6. The pharmaceutical dosage form according to claim 3 in the form of a soft gelatine capsule comprising 100 mg of active substance

free base equivalent selected from the group consisting of compositions A, B and C:

Ingredients	Formulation A mg per capsule	Formulation B mg per capsule	Formulation C mg per capsule
Active Substance*	120.40	120.40	120.40
Triglycerides, Medium-chain	81.90	107.40	106.8
Hard fat	76.50	51.00	51.00
Lecithin	1.20	1.20	1.80
Gelatin	111.58	111.58	111.58
Glycerol 85%	48.79	48.79	48.79
Titanium dioxide	0.36	0.36	0.36
Iron oxide A	0.06	0.06	0.06
Iron oxide B	0.17	0.17	0.17
Total Capsule Weight	440.96	440.96	440.96.

7. The pharmaceutical dosage form according to claim 3 in the form of a soft gelatine capsule comprising 125 mg of active substance free base equivalent selected from the group consisting of compositions A, B and C:

Ingredients	Formulation A mg per capsule	Formulation B mg per capsule	Formulation C mg per capsule
Active Substance*	150.50	150.50	150.50
Triglycerides, Medium-chain	102.375	134.25	133.5
Hard fat	95.625	63.75	63.75
Lecithin	1.50	1.50	2.25
Gelatin	142.82	142.82	142.82
Glycerol 85%	62.45	62.45	62.45
Titanium dioxide	0.47	0.47	0.47
Iron oxide A	0.08	0.08	0.08
Iron oxide B	0.22	0.22	0.22
Total Capsule Weight	556.04	556.04	556.04.

8. The pharmaceutical dosage form according to claim 3 in the form of a soft gelatine capsule comprising 150 mg of active substance free base equivalent selected from the group consisting of compositions A, B and C:

Ingredients	Formulation A mg per capsule	Formulation B mg per capsule	Formulation C mg per capsule
Active Substance*	180.60	180.60	180.60
Triglycerides, Medium-chain	122.85	161.10	160.20
Hard fat	114.75	76.50	76.50
Lecithin	1.80	1.80	2.70
Gelatin	142.82	142.82	142.82
Glycerol 85%	62.45	62.45	62.45
Titanium dioxide	0.47	0.47	0.47
Iron oxide A	0.08	0.08	0.08
Iron oxide B	0.22	0.22	0.22
Total Capsule Weight	626.04	626.04	626.04.

9. The pharmaceutical dosage form according to claim 3 in the form of a soft gelatine capsule comprising 200 mg of active substance free base equivalent selected from the group consisting of compositions A, B and C:

Ingredients	Formulation A mg per capsule	Formulation B mg per capsule	Formulation C mg per capsule
Active Substance*	240.80	240.80	240.80
Triglycerides, Medium-chain	163.30	214.80	216.00
Hard fat	153.50	102.00	102.00
Lecithin	2.40	2.40	1.20
Gelatin	203.19	203.19	203.19
Glycerol 85%	102.61	102.61	102.61
Titanium dioxide	0.57	0.57	0.57
Iron oxide A	0.90	0.90	0.90
Iron oxide B	0.90	0.90	0.90
Total Capsule Weight	868.17	868.17	868.17.

10. The pharmaceutical dosage form according to claim 3 in the form of a soft gelatine capsule comprising 100 mg of active substance free base equivalent selected from the group consisting of compositions A, B and C:

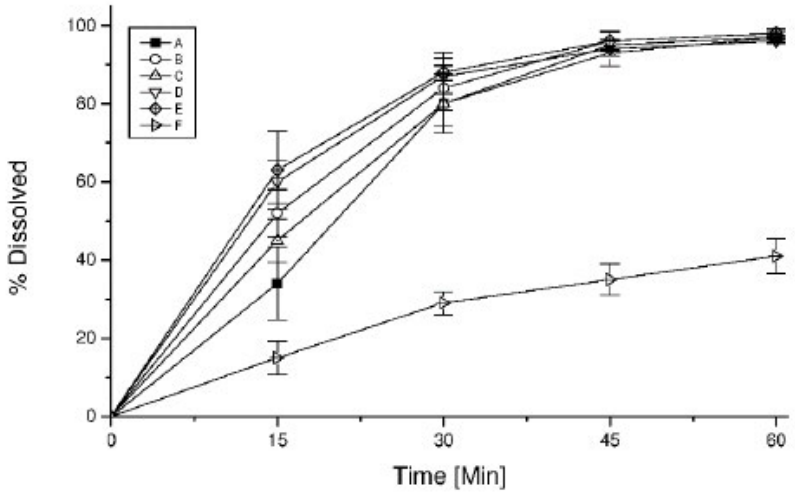
105. Independent claim 1 of the ’323 patent recites a “pharmaceutical dosage form which is a viscous lipid suspension formulation comprising 10 to 50 wt. % of the active substance 3-Z-[1-(4-(N-((4-methyl-piperazin-1-yl)-methycarbonyl)-N-methyl-amino)-anilino)-1-phenyl-methylene]-6-methoxycarbonyl-2-indolinone-monoethanesulphonate, [i.e., nintendanib ethanesulphonate] 10 to 70 wt.% of medium chain triglycerides; 10 to 30 wt.% of hard fat; and

0.25 to 2.5 wt.% of lecithin, which delivers an immediate release profile in which not less than 70% (Q65%) of the active substance is dissolved in 60 minutes in vitro under the following in vitro dissolution conditions according to European Pharmacopeia 6.2: Apparatus 2 (paddle), dissolution medium with 0.1 M HCl (pH 1) and stirring speed of 50 to 150 rpm, at a temperature of 37° C." *Id.* at cl. 1.

106. The '323 specification states that "[l]ecithin is a common excipient for carrier-systems in soft gelatin capsules. It is used as a glidant of the highly concentrated suspension during encapsulation, prevents blocking of ducts and pumps and ensures high mass uniformity of the encapsulated formulation." *Id.* at col. 12, ll. 53–57. In addition, lecithin "acts as a surfactant, which may improve distribution of the formulation-droplets during *in-vitro* dissolution testing as well as *in-vivo* for drug resorption. Furthermore, it may also improve wetting of the active substance crystals." *Id.* at col. 12, ll. 57–62.

107. The specification further provides that "[l]ecithin, up to a certain content, is useful to improve the dissolution behaviour of the finished capsules. Exceeding amounts do not show an additional benefit during *in-vitro* dissolution testing, as shown in Figure 2." *Id.* at col. 12, ll. 64–67. Figure 2, reproduced below, shows the *in-vitro* dissolution behavior (measured as % dissolution) over time (in minutes) of 150 mg nintedanib soft gelatin capsules comprising: (A) 30% of the preferred amount of lecithin; (B); 75% of the preferred amount of lecithin; (C) 90% of the preferred amount of lecithin; (D) 100% of the preferred amount of lecithin; (E) 200% of the preferred amount of lecithin; and (F) 0% lecithin.

Figure 2 of 10



108. During the prosecution of the ’323 patent, the examiner rejected certain pending claims as obvious, or anticipated by the prior art. *See* Exhibit N, September 7, 2017 Office Action at 1, 2–7. In response, the applicant amended claim 1 to further require a “pharmaceutical dosage form which is a viscous lipid suspension formulation” and to further specify that the formulation comprises “10 to 50 wt.% of the active substance 3-Z[1-(4-(N-((4-methyl-piperazin-1-yl)-methylcarbonyl)-N-methyl-amino)-anilino)-1-phenyl-methylene]-6-methoxycarbonyl-2-indolinone-monoethanesulphonate; 10 to 70 wt.% of medium chain triglycerides; 10 to 30 wt.% of hard fat; and ***0.25 to 2.5 wt.% of lecithin***.” Exhibit O, February 8, 2018 Response at 3 (emphasis added).

109. Furthermore, in a June 4, 2018 Response, the applicant amended claim 1 to recite a “pharmaceutical dosage form comprising a viscous lipid suspension formulation.” Exhibit P, June 4, 2018 Response at 2 (emphasis in original). In addition, the applicant argued that support

for a "viscous lipid suspension formulation" could be found on page 17, ll. 1–9 and page 18, ll. 14–19 of the application's specification. *Id.* at 9. The applicant also agreed to file a terminal disclaimer to the '756 patent. *Id.* at 10.

110. The examiner allowed the claims in a Notice of Allowance dated January 17, 2018, with no further explanation. Exhibit Q, July 5, 2018 Notice of Allowance at 2–3.

111. Claims 1–10 of the '323 patent require, either directly or indirectly, a lipid suspension of nintedanib ethanesulphonate comprising "0.25 to 2.5 wt.% of lecithin."

112. [redacted]

113. [redacted]

114. [redacted] and therefore do not literally infringe each of claims 1–10 of the '323 patent. *See* Exhibit H, Excerpt of Cipla's Shared Materials.

115. The ANDA specification may directly resolve the infringement inquiry because it defines a proposed generic product such that it either meets the limitations of an asserted patent claim or is outside the scope of the claim. *See Ferring B.V. v. Watson Labs., Inc.-Florida*, 764 F.3d 1401, 1408 (Fed. Cir. 2014).

Cipla Does Not Infringe the '323 Patent Under the Doctrine of Equivalents

116. Concluding that using any weight percent amount of lecithin in a nintedanib suspension that is outside the claimed range of 0.25% to 2.5% w/w is equivalent to using 0.25 to 2.5% w/w of lecithin would vitiate this claim limitation. *See Warner-Jenksinson*, 520 U.S. at 29. Moreover, the patentee has explicitly touted the advantages of using 0.25 to 2.5% w/w of lecithin in a nintedanib suspension. The '323 specification provides that "lecithin, ***up to a certain content***,

is useful to improve the dissolution behaviour of the finished capsules." Exhibit M, '323 patent at col. 12, ll. 64–67 (emphasis added). The specification further states that amounts of lecithin exceeding those claimed by the '323 patent "do not show an additional benefit during *in-vitro* dissolution testing." *Id.* Because nintedanib suspensions containing more than 2.5% w/w of lecithin were foreseeable to the patentee but not literally claimed in the '323 patent, a finding of equivalents would vitiate this claim limitation. *See, e.g.*, *Sage Products, Inc.*, 126 F.3d at 1424–25. As such, a nintedanib suspension comprising a weight percent amount of lecithin outside the claimed range of 0.25% to 2.5% w/w is substantially different than, and not equivalent to, a suspension with 0.25% to 2.5% w/w lecithin.

117. Furthermore, nintedanib suspensions comprising more than 2.5% w/w of lecithin have been disclaimed from this application and, to the extent not otherwise claimed in related applications, dedicated to the public by the patentee. The specification of the '323 patent explicitly discloses nintedanib suspensions comprising up to 10 weight % lecithin (col. 13, ll. 1–3), and yet the patentee only claimed suspensions containing 0.25 to 2.5% w/w/ lecithin. Because nintedanib suspensions containing more than 2.5% w/w of lecithin are explicitly disclosed but not specifically claimed by the patentee in claims 1–10 of the '323 patent, such compositions have been dedicated to the public and disclaimed by the patentee as a substantial equivalent. *See Maxwell*, 86 F.3d at 1107. Therefore, a nintedanib suspension comprising a weight percent amount of lecithin outside the claimed range of 0.25% to 2.5% w/w has been disclaimed by the patentee as a substantial equivalent to a suspension with 2.5% w/w lecithin.

118. Finally, the doctrine of prosecution history of estoppel bars the patentee from asserting substantial equivalence between a nintedanib suspension containing 0.25% to 2.5% w/w lecithin and a suspension containing a weight percent amount of lecithin outside the claimed range

of 0.25% to 2.5% w/w. During prosecution of the '323 patent, and in response to anticipation and obviousness rejections, the patentee amended the claims to specifically require a "pharmaceutical dosage form which is a viscous lipid suspension formulation comprising 10 to 50 wt.% of the active substance 3-Z[1-(4-(N-((4-methyl-piperazin-1-yl)-methylcarbonyl)-N-methyl-amino)-anilino)-1-phenyl-methylene]-6-methoxycarbonyl-2-indolinone-monoethanesulphonate; 10 to 70 wt.% of medium chain triglycerides; 10 to 30 wt.% of hard fat; and ***0.25 to 2.5 wt.% of lecithin***." Exhibit O, February 8, 2018 Response at 3 (emphasis added). The patentee made this amendment to argue that the prior art cited by the examiner did not teach or even suggest using lecithin, let alone 0.25 to 2.5% w/w of lecithin, in a nintedanib suspension. *Id.* at 12–13 ("Therefore, one skilled in the art would find no motivation in Park et al. to make or use a ***viscous liquid formulation comprising*** inter alia 10 to 30 wt.% of hard fat triglycerides and ***0.25 to 2.5% of lecithin*** as recited in amended claim 1") (emphasis added).

119. It was only after the applicant narrowed the scope of the claims that the examiner allowed the claims over the prior art of record. This narrowing of the claims was a clear and unmistakable surrender of all components and amounts other than those components and amounts listed in the claim. As a result, the patentee cannot recapture the scope of the claims given up during prosecution. *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1251 (Fed. Cir. 2000).

COUNT I

(Declaratory Judgment of Non-infringement of the '756 patent)

120. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 119 of this Complaint as if fully set forth herein.

121. The claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, 21 U.S.C. § 355(j)(5)(C), and 35 U.S.C. § 271(e)(5).

122. Boehringer listed the ’756 patent in the Orange Book in connection with Ofev.

123. Cipla filed ANDA No. 212609 with a PIV certification stating, among other things, that the ’756 patent is not and will not be infringed by Cipla’s ANDA Products.

124. Cipla intends to sell its Cipla’s ANDA Products, as described in ANDA No. 212609, once it receives final approval from FDA.

125. There is a real, actual and continuing justiciable case and controversy between Cipla and Boehringer relating to the infringement of the ’756 patent by Cipla’s ANDA Products.

126. For reasons explained above and in Cipla’s Notice Letter and detailed statement, the manufacture, use, offer for sale, sale, and/or importation of Cipla’s ANDA Products will not infringe the ’756 patent. *See* Exhibit C, Cipla’s Notice Letter.

127. Accordingly, Cipla seeks and is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, and/or importation of Cipla’s ANDA Products do not and will not infringe, directly or indirectly, any valid claim of the ’756 patent.

COUNT II

(Declaratory Judgment of Non-infringement of the ’323 patent)

128. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 127 of this Complaint as if fully set forth herein.

129. The claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, 21 U.S.C. § 355(j)(5)(C), and 35 U.S.C. § 271(e)(5).

130. Boehringer listed the ’323 patent in the Orange Book in connection with Ofev.

131. Cipla filed ANDA No. 212609 with a PIV certification stating, among other things, that the '323 patent is not and will not be infringed by Cipla's ANDA Products.

132. Cipla intends to sell its Cipla's ANDA Products, as described in ANDA No. 212609, once it receives final approval from FDA.

133. There is a real, actual and continuing justiciable case and controversy between Cipla and Boehringer relating to the infringement of the '323 patent by Cipla's ANDA Products.

134. For reasons explained above and in Cipla's Notice Letter and detailed statement, the manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Products will not infringe the '323 patent. *See* Exhibit C, Cipla's Notice Letter.

135. Accordingly, Cipla seeks and is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Products do not and will not infringe, directly or indirectly, any valid claim of the '323 patent.

Prayer for Relief

WHEREFORE, Cipla prays that this Court enter judgment against Defendants:

A. Declaring that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Products do not and will not directly or indirectly infringe any valid and enforceable claim of the '756 patent, either literally or under the doctrine of equivalents;

B. Declaring that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Products do not and will not directly or indirectly infringe any valid and enforceable claim of the '323 patent, either literally or under the doctrine of equivalents;

C. Awarding Cipla its costs and expenses incurred in this action;

D. Declaring that this an exceptional case in favor of Cipla and awarding Cipla its reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

E. Awarding Cipla such other and further relief as the Court may deem proper.

Dated: March 4, 2022

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